K120472

Hologic, Inc.
35 Crosby Drive, Bedford, MA 01730 USA
Main: +1.781.999.7300 Fax: +1.781.280.0669

JUN 22 2012

B. Administrative Information

B.1 510(k) Summary of Safety & Effectiveness

(as required by 21 CFR §807.92c)

Date Prepared: February 15, 2012
Submitted by:

Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730 USA

Name, Title and Phone Number of Contact:

Catherine A. Williams
Director, Regulatory Affairs
Phone: (408) 352-0201
FAX: (408) 352-0101
Email: catherine.williams@hologic.com

Trade Name and Common Name:

Trade Name:	Quantra™
Software Version:	2.0
Common Name:	Picture Archiving and Communications System

Device Classification:

Regulatory Class:	II
Classification Panel:	Radiology
Image Processing System	21 CFR §892.2050
Product Code	90-LLZ

Predicate Devices:

The predicate devices for Quantra software are certain software functions contained in the following devices:

K082483, September 12, 2008	Quantra (Volumetric Assessment) [Hologic, Inc.]
K050196, February 24, 2005	Sectra IDS5 Workstation [Sectra Imtec AB]
K102556, October 7, 2010	Volpara Imaging Software [Matakina Technology Limited]

Device Description:

Quantra is a software application that estimates breast tissue volume and area density. The estimations are made from images acquired using digital breast X-ray systems.

Quantra has been designed and will be manufactured in accordance with the following standards:

- ISO 14971 Medical Devices – Application of Risk Management to Medical Devices
- ISO 62304 Medical Device Software – Software Life Cycle Processes

The performance of the software is also tested in accordance with Hologic's SOPs and testing procedures to demonstrate adequate performance.

Intended Use:

Quantra™ is a software application intended for use with images acquired using digital breast X-ray systems. Quantra calculates volumetric breast density as a ratio of fibroglandular tissue and total breast volume estimates; and area breast density as a ratio of fibroglandular tissue area and total breast area estimates. It segregates breast density into BI-RADS-like breast composition categories, which may be useful in the reporting of consistent breast composition values as mandated by certain state regulations. Quantra provides these numerical values for each image, breast, and subject, to aid radiologists in the assessment of breast tissue composition. Quantra produces adjunctive information; it is not an interpretive or diagnostic aid. Quantra runs on a Windows platform.

Technological Characteristics:

Quantra is a software application that processes digital mammography images. The device does not contact the patient, nor does it control any life-sustaining devices.

Performance/Bench Testing:

The volumetric breast density measures were validated by demonstrating correlation both with the Quantra predicate device and with MRI cases of the same patients. The measures also were compared to the mode (most common) BI-RADS density rating from 15 radiologists on a large database of cases. Finally, the Vbd values were compared across a large population of cases from Hologic (Selenia and Dimensions), GE (Senographe and Essential), and Siemens (Mammomat Novation) FFDMs to ensure the distributions were similar.

The area breast density measure was validated using a correlation-based assessment to compare Quantra values with dense area measurement based on hand-drawn dense areas annotated by an expert using the predicate device Sectra IDS5 workstation. The measure also was compared to the mode (most common) BI-RADS density rating from 15 radiologists on a large database of cases. Finally, the Abd values were compared across a large population of cases from Hologic (Selenia and Dimensions), GE (Senographe and

Essential), and Siemens (Mammomat Novation) FFDMs to ensure the distributions were similar.

The volumetric breast density (Vbd) and volume of fibroglandular tissue (Vfg) values were used to create two scores (Vbd-score and Vfg-score), which reflect the number of standard deviations between a subject's Vbd or Vfg value and the corresponding mean value of approximately 1,000 patients in a reference database.

The BI-RADS-like breast composition measure (Q_abd), similar to the density grade measure in the Matakina predicate device, was evaluated based on a comparison of Q_abd with BI-RADS values assigned by 15 radiologists on a large set of digital mammography cases. The continuous q_abd score was compared to the mean value of the 15 radiologists on the same large database of cases described above. Finally, the q_abd values were compared across a large population of cases from Hologic (Selenia and Dimensions), GE (Senographe and Essential), and Siemens (Mammomat Novation) FFDMs to ensure the distributions were similar.

All Quantra density measures were evaluated statistically between CC and MLO views of the same breast and left and right breasts of the same women, using a substantially large number of images from Hologic (Selenia and Selenia Dimensions), GE (Senographe and Senographe Essential), and Siemens (Mammomat Novation) digital breast X-ray systems).

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device. Risk management is ensured via a risk analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing.

Conclusion:

The 510(k) Premarket Notification for Quantra contains adequate information and data to enable FDA/ CDRH to determine substantial equivalence to the predicate devices.

The submission contains the results of a hazard analysis and the "Level of Concern" for potential hazards has been classified as "Moderate".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUN 22 2012

Ms. Catherine A. Williams
Director, Regulatory Affairs
Hologic, Inc.
35 Crosby Drive
BEDFORD MA 01730

Re: K120472
Trade/Device Name: Quantra™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 18, 2012
Received: May 21, 2012

Dear Ms. Williams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

B.2 Indication(s) for Use Statement

510(k) Number (if known): K120472

Device Name: Quantra™

Indications for Use:

Quantra™ is a software application intended for use with images acquired using digital breast X-ray systems. Quantra calculates volumetric breast density as a ratio of fibroglandular tissue and total breast volume estimates; and area breast density as a ratio of fibroglandular tissue area and total breast area estimates. It segregates breast density into BI-RADS-like breast composition categories, which may be useful in the reporting of consistent breast composition values as mandated by certain state regulations. Quantra provides these numerical values for each image, breast, and subject, to aid radiologists in the assessment of breast tissue composition. Quantra produces adjunctive information; it is not an interpretive or diagnostic aid. Quantra runs on a Windows platform.

Prescription Use (Part 21 CFR§801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR §807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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